

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
	)	
	)	Plaintiff,
	)	
	)	Civil Action No.: 06-222 JJF
v.	)	
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
	)	Defendant.
	)	
_____	)	

DECLARATION OF MARY B. MATTERER IN OPPOSITION TO  
PLAINTIFF'S MOTION TO COMPEL

MARY B. MATTERER (I.D. No. 2696)  
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Attorneys for Defendant  
IMPAX LABORATORIES, INC.

September 25, 2006

I, Mary B. Matterer, declare:

1. I am a partner at the law firm of Morris, James, Hitchens & Williams LLP, counsel to Defendant Impax Laboratories, Inc. ("Impax") in this matter.
2. Attached hereto as Exhibit 1 is a copy of a letter of September 7, 2006 from Samuel F. Ernst, counsel to Impax, to Linda A Wadler, counsel to Plaintiff Wyeth ("Wyeth").
3. Attached hereto as Exhibit 2 is a copy of a letter of September 13, 2006 from Jessica R. Wolff, counsel to Impax, to Ms. Wadler.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on this twenty-fifth day of September, 2006 at Wilmington, Delaware.



MARY B. MATTERER (I.D. No. 2696)

# Exhibit 1

# HellerEhrman<sub>LLP</sub>

September 7, 2006

Samuel F. Ernst  
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40443.0005

Linda A. Wadler, Esq.  
Finnegan Henderson Farabow Garrett  
& Dunner LLP  
901 New York Ave., NW  
Washington, DC 20001-4413

**Re: *Wyeth v. Impax Laboratories, Inc.*, Civil Action No. 06-222 (D. Del.)**

Dear Linda:

This letter is in response to your letter of September 7, 2006.

Because the parties do not appear to be making progress on their respective discovery disputes through the current campaign of dueling letters, on August 28, 2006 we sent you a letter suggesting that the parties telephonically meet and confer and proposing three windows of time during which Impax was available for a meet and confer. Your letter of August 29 did not respond to this offer to meet and confer. Accordingly, in response to your August 29 letter I called you on the phone and left a voicemail asking for a telephonic meet and confer. Your suggestion that we have not responded to your letter of August 29 is, therefore, not a fair characterization. It would certainly be improper for Wyeth to file a motion to compel surrounding these discovery disputes without telephonically meeting and conferring, as you threaten in your letter of September 7.

In any event, we are pleased that you have now agreed to telephonically meet and confer tomorrow. You stated that you were available between the hours of 12 noon and 5 p.m. EST. As I stated in my voice-mail to you earlier today, we are available tomorrow, Friday, September 8, 2006 at 3 p.m. EST. We will call you for a meet and confer at that time.

Your document request for all proposed, experimental, and commercial products containing the active ingredient venlafaxine hydrochloride is unduly broad and calls for the production of documents that are irrelevant to this litigation. As we stated in our letter of August 21, we will produce documents regarding the products that are accused in this litigation – *i.e.*, the products that are the subject of ANDA 78-057. You suggest that tests of other products may have been undertaken in Impax's development of the accused products.

Heller Ehrman LLP 333 Bush Street San Francisco, CA 94104-2878 [www.hellerehrman.com](http://www.hellerehrman.com)

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Anchorage	Beijing	Hong Kong	Los Angeles	Madison, WI	New York	San Diego	San Francisco	Seattle
Silicon Valley	Singapore	Washington, D.C.						

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Linda A. Wadler, Esq.  
September 7, 2006  
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But Impax has said that it will produce documents related to its research and development of the accused products in response to Wyeth's Document Request Number 5.

We maintain that documents regarding Impax's awareness of the patents-in-suit are irrelevant to this litigation now that Wyeth has withdrawn its claim of willful infringement. Infringement will be decided based on a determination as to whether Impax's accused products contain, literally or by equivalence, every limitation of the asserted claims; not based on Impax's awareness of the patents-in-suit or lack thereof. Nor does the validity of Wyeth's patents, including the question as to whether Wyeth's commercial embodiments have enjoyed commercial success, depend on Impax's awareness of the patents. You suggest that documents regarding Impax's awareness of the patents-in-suit are relevant to the question as to whether Impax copied Wyeth's alleged inventions in developing the accused products. But Impax has agreed to produce documents related to the development of the accused products; any documents evidencing copying would be produced in response to these document requests.

Your letter inquires into whether Impax will produce additional documents other than its ANDA. As described in our responses to Wyeth's document requests, we will produce responsive, non-privileged documents that we are aware of by the October 10 deadline provided for in the Court's Scheduling Order.

With regard to your concern surrounding our general objections to your document requests and interrogatories, the general objections merely restate the limits on our discovery obligations provided for in Federal Rule of Civil Procedure 26(b) and are entirely proper. We note that Wyeth also stated a general objection in response to Impax's discovery requests that it objects to interrogatories and document requests that impose "any obligation not required by the Federal Rules of Civil Procedure." Is Wyeth prepared to identify documents or information it is withholding on this basis as it demands of Impax? We fail to understand Wyeth's concerns with regard to our general objections.

You have also inquired into specific objections we made regarding vague and ambiguous terms in Wyeth's Document Requests Nos. 5-9, 16-17, 26-27, 32-33, 47, 56-57, 59, 62-63, 69-75, and 84-85. Although we objected to the undefined terms Wyeth employed in these document requests, we also responded that we would produce responsive, non-privileged documents in response to each of these document requests. Accordingly, we fail to understand what, precisely, Wyeth is complaining about.

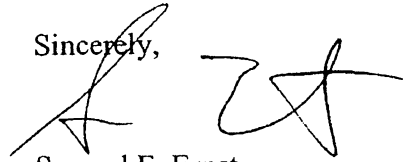
We believe that in this letter and in our letters of August 21 and August 28 we have responded to each of the issues raised by Wyeth with regard to Impax's discovery responses. If Wyeth feels this is incorrect, we look forward to clarifying any further issues during tomorrow's meet and confer. We note that Wyeth has not responded substantively to each of

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Linda A. Wadler, Esq.  
September 7, 2006  
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the issues Impax raised regarding Wyeth's discovery responses in Impax's letter of August 21, but we will await any further response from Wyeth until tomorrow's meet and confer.

Sincerely,

A handwritten signature in black ink, appearing to be 'SFE', written over a horizontal line.

Samuel F. Ernst

# **Exhibit 2**

# HellerEhrman<sub>LLP</sub>

September 13, 2006

**VIA EMAIL TRANSMISSION**

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**Re: Wyeth v. Impax Laboratories, Inc.  
U.S. District Court, District of Delaware  
Civil Action No. 06-222**

Dear Linda:

The purpose of this letter is to follow up on our meet and confer of Friday, September 8, 2006. As I indicated in the call, we will endeavor to provide comments this week to your voluminous changes to the proposed Protective Order.

You also requested that I inform you whether Impax was withholding any documents in response to particular Requests for Production, due to Impax's objection that the request was overly broad and unduly burdensome. As indicated in our Response to Wyeth's First Request for Production of Documents and Things (Nos. 1-87), Impax will not search for and produce documents in response to Requests for Production Numbers 57, 67, 73, and 81, which are grossly overly broad and unduly burdensome. Furthermore, regarding Request No. 81, to the extent that Impax has materials from third parties such as IMS, it is likely that Wyeth already has this information. In addition, we are informed that third parties, like IMS, contractually prevent Impax from sharing this information.

We note that Wyeth has also raised general objections without specifying whether it has withheld documents and if so, which documents it has withheld based on these general objections. *See, e.g.*, Wyeth's general objections 1, 15-17, and Mr. Ernst's letter of September 7, 2006. Please verify that Wyeth is not withholding documents based on its general objections as Wyeth has demanded of Impax.

Although you are unable to articulate how the documents requested by Request No. 80 are relevant to the instant lawsuit and you can easily obtain them from public records, in the



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spirit of cooperation Impax will be producing non-privileged documents in response to this request.

You also asked me to inform you whether Impax worked on an immediate release venlafaxine product. I am informed by Impax that it did not. Moreover, as I reiterated in our conversation, Impax will not produce documents in Impax's possession concerning an extended release venlafaxine formulation that do not relate to Impax's ANDA 78-057 product. This is the only product that allegedly infringes Wyeth's patent claims. Any documents on other formulations are not relevant to Wyeth's allegations of infringement. Impax stands by its objection to producing documents that do not relate to Impax's ANDA 78-057 product.

I can confirm that Impax will produce non-privileged responsive documents on Impax's research and development of the ANDA 78-057 product, such as *in vitro* dissolution studies.

As explained in detail in previous letters and as I discussed in the call, Wyeth has withdrawn its claim for willfulness and thus discovery on willfulness and exceptional case issues, including documents showing an awareness of the patents-in-suit, is not proper. We have provided case law to you on this subject. Your argument that you need non-privileged documents showing Impax's awareness of the patents-in-suit to prove copying and infringement under the doctrine of equivalents is disingenuous. The strongest evidence on whether there is copying is a comparison of the two formulations. Such comparison makes clear that Impax's formulation is not a copy of Wyeth's patented formulation with a microcrystalline cellulose drug matrix. While we believe that Wyeth is completely foreclosed from arguing infringement under the doctrine of equivalents, assuming it is not, Wyeth will have to prove infringement under the doctrine of equivalents through proof that aspects of Impax's formulation perform substantially the same function in substantially the same way to achieve substantially the same result as the missing microcrystalline cellulose. Such evidence will not come from an awareness of the patents-in-suit.

Contrary to your assertions in your letter, I did inform you that Impax was relying on the withdrawal of Wyeth's willfulness claim for withholding documents. In addition, I did inform you that Impax was continuing to rely on its objections as stated in its Response to Plaintiff's Requests for Production (Numbers 1-87).

I also can confirm that Impax intends to begin producing documents or making them available for inspection before October 10, 2006. Unlike Wyeth, Impax does not have the

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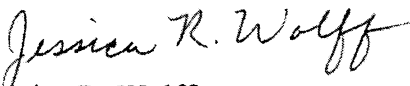
benefit of having gathered and previously produced some of the responsive documents in previous litigations.

By the end of this week, we look forward to receiving Wyeth's responses concerning:

1) Our proposal limiting the discoverability of attorney-expert communications;  
and

2) The meaning of clinical "data compilations" in your general objections to Impax's Second Request for Production of Documents (See Number 15).

Sincerely,

  
Jessica R. Wolff

cc: Mary Matterer, Esq.  
Sam Ernst, Esq.

SD 835802 v2

**CERTIFICATE OF SERVICE**

I hereby certify that on the 25<sup>th</sup> day of September, 2006, I electronically filed the foregoing document, **DECLARATION OF MARY B. MATTERER IN OPPOSITION TO PLAINTIFF'S MOTION TO COMPEL**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld  
Karen Jacobs Loudon  
Morris Nichols Arsht & Tunnell  
1201 N. Market Street  
Wilmington, DE 19801

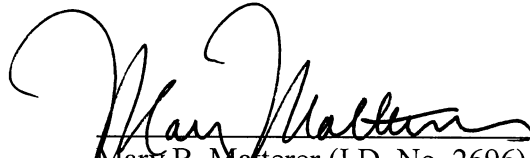
Additionally, I hereby certify that on the 25<sup>th</sup> day of September, 2006, the foregoing document was served as indicated on the following:

**VIA EMAIL AND HAND DELIVERY**

Jack B. Blumenfeld  
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Attorneys for IMPAX LABORATORIES, INC.